



PATENT

45437

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	:	
	:	
Frank S. D'AMELIO, Sr. et al.	:	Art Unit: 1614
	:	
Serial No.: 10/791,290	:	Examiner: L. Roberts
	:	
Filed: March 3, 2004	:	
	:	
For: METHOD AND COMPOSITION FOR	:	
TREATING ORAL BACTERIA AND	:	
INFLAMMATION	:	

DECLARATION UNDER 37 C.F.R. § 1.131

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

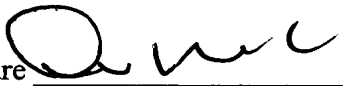
We, Frank S. D'Amelio, Sr. and Youssef W. Mirhom, Ph.D., declare as follows:

1. We are the applicants on the above-identified Application;
 2. We are aware of U.S. Patent Application Publication No. 2005/0158252, published July 21, 2005, having a filing date of December 21, 2004 and claiming priority to Provisional Application No. 60/532,303, filed December 22, 2003.
 3. We conceived and reduced the invention to practice prior to December 23, 2003.
- Attached as Exhibit A is a Batch Report as written documentation of the invention dated before December 23, 2003 describing the conception and reduction to practice of the invention for an oral composition according to the present invention. The date of this document is deleted. Our work continued diligently until the filing of this patent application on March 3, 2004.


The undersigned declare further that all statements made herein of their own knowledge are true and that all statements made on information and belief are believed to be true; and

further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

(1) Frank S. D'Amelio, Sr.

Signature 
Date: 04/03/07

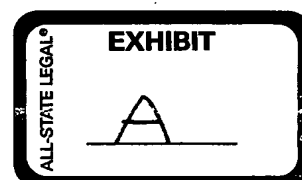
(2) Youssef W. Mirhom, Ph.D.

Signature 
Date: 03.29.07



Batch Record

Product PerioCleanse			Product Code # RD1008		Lot # MQ-005-145	
Batch Size 124.5 Kg = 100 Lit			Theoretical Yield 100 Lit		Actual Yield 98 Lit	
					Date	
					Revised Date	
ITEM	AMOUNT	% w/w	INGREDIENT		PROD. CODE	LOT #
1	1.002 Kg	0.800%	Aloe vera Phytogel		4044	010379
2	0.167 Kg	0.134%	Folic Acid		8014F	2-0055
3	0.417 Kg	0.330%	NE, Prickly Ash Bark Extract		10825	001241
4	1.667 Kg	1.338%	NE, Calendula Extract (Marigold)		10650	001768
5	1.267 Kg	1.017%	NE, Echinacea purp. Tops		10392	002162
6	0.627 Kg	0.504%	NE, Gotu Kola Extract		10500	002286
7	1.267 Kg	1.017%	NE, Chamomile Extract		10245	001763
8	0.862 Kg	0.692%	Phytoplenolin Extract in BG		RD0080	YM001.146
9	0.0832 Kg	0.067%	NE, Olive Leaf Extract		10713	980642
10	0.033 Kg	0.026%	NE, Black Walnut Hulls Extract		10110	991125B
11	0.042 Kg	0.034%	NE, Grape Fruit Seed Extract		8016D	2-2488
12	0.020 Kg	0.016%	Green Tea, PE 50% Polyphenols			2-2812
FOR CALCULATIONS						
			PerioCleanse Specific gravity		98 Lit 1.2450	
PROCEDURE:						
I. Take all NE's i.e., 3, 4, 5, 6, 7, 8, 9, 10, 11 in 10 Kg Glycerin and autoclave to sterilize.						
II. In a separate container, make a paste of 1, 2, 22 with 21 then add 10 Kg Glycerin and mix well.						
III. Then in a suitable container take 70 Kg Glycerin and add slowly II with mixing. (Make sure that this paste does not go into the bottom tube without mixing). Warm to dissolve completely. Homogenize well by mixing.						
IV. Then add 12 & 13 one by one with mixing to III. Warm to dissolve, followed by the addition of I gradually with mixing then stir to cool.						
						Continued on P-2





Continued P-2

Batch Record

Product PerioCleanse			Product Code # RD1008		Lot # MQ-005-145	
Batch Size 124.5 Kg = 100 Lit			Theoretical Yield 100 Lit		Actual Yield 98 Lit	
					Date	
					Revised Date	
ITEM	AMOUNT	% w/w	INGREDIENT		PROD. CODE	LOT #
13	833 mg*	0.000669 %	Chlorophyll KK		Food, Flavor & Pharm. Ingredient	L-43652
14	2.700 Kg	2.168%	Peppermint Oil		8033D	2-3666
15	0.379 Kg	0.304%	Oregano Oil		8031K	2-0833
16	0.223 Kg	0.179%	Lavender Oil		8019B	2-3076
17	0.175 Kg	0.140%	Clove Bud Oil		8031M	2-2338
18	0.076 Kg	0.061%	Thyme Oil		8031L	2-0987
19	0.076 Kg	0.061%	Eucalyptus Oil		8013A	2-0846
20	0.044 Kg	0.035%	Cinnamon Bark Oil		8005H	2-2811
21	1.000 Kg	0.803%	Bio-Saponin Conc.		10076	001838
22	0.032 Kg	0.026%	Co-Enzyme Q-10		Essential Fine Ingredient	
23	111.98 Kg	89.879%	Glycerin			
FOR CALCULATIONS						
			PerioCleanse		.98 Lit	
			Specific gravity		1.2450	
PROCEDURE:						
V. Upon cooling, add all the volatile oils one by one i.e., 14-20 and remaining Glycerin 21.98 Kg into the container with mixing. Mix well to give Homogeneous Formula.						